



MASSACHUSETTS

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Medical Policy

Isolated Limb Perfusion/Infusion for Malignant Melanoma

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 124

BCBSA Reference Number: 7.01.12A (For Plans internal use only)

NCD/LCD: NA

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Isolated Limb Perfusion (ILP)

When used as a therapeutic treatment of local recurrence of nonresectable melanoma (i.e., satellite lesions or “in transit” melanoma), ILP with melphalan may be considered [MEDICALLY NECESSARY](#).

When used as an adjuvant treatment of surgically treated locally recurrent melanoma with no other evidence of disease, ILP with melphalan is considered [INVESTIGATIONAL](#).

ILP in conjunction with hyperthermia or isolated limb perfusion using melphalan in conjunction with tumor necrosis factor or interferon gamma is considered [INVESTIGATIONAL](#).

When used as an adjuvant treatment of surgically treated primary malignant melanoma with no clinical evidence of disease, ILP with melphalan is considered [NOT MEDICALLY NECESSARY](#).

Isolated Limb Infusion (ILI)

When used as a therapeutic treatment of local recurrence of nonresectable melanoma (i.e., satellite lesions or “in transit” melanoma), ILI with melphalan may be considered [MEDICALLY NECESSARY](#).

ILI in the treatment of melanoma is considered [INVESTIGATIONAL](#) for all other indications.

One treatment with ILP with melphalan may be [MEDICALLY NECESSARY](#) as a therapeutic treatment of local recurrence of nonresectable melanoma (i.e. satellite lesions or “in transit” melanoma.)

Treatment of recurrence of disease with ILP with melphalan may be **MEDICALLY NECESSARY** as a therapeutic treatment of local recurrence of nonresectable melanoma (i.e. satellite lesions or “in transit” melanoma) only, when a patient has had an incomplete response after the first procedure.

ILI with melphalan may be **MEDICALLY NECESSARY** as a therapeutic treatment of local recurrence of nonresectable melanoma (i.e., satellite lesions or “in transit” melanoma.)

Note: Due to the reported lower morbidity with isolated limb infusion, patients may receive more than one treatment, to offer a hyperfractionated regimen.

Isolated limb perfusion is **INVESTIGATIONAL** for the following indications:

- With melphalan
 - Adjuvant treatment of surgically treated locally recurrent melanoma with no other evidence of disease, and
 - In conjunction with TNF (tumor necrosis factor) or interferon gamma.
- With hyperthermia, or
- For the treatment of melanoma for all other indications.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO BlueSM	Prior authorization is not required .
Medicare PPO BlueSM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
36823	Insertion of arterial and venous cannula(s) for isolated extracorporeal circulation including regional chemotherapy perfusion to an extremity, with or without hyperthermia, with removal of cannula(s) and repair of arteriotomy and venotomy sites

The following **ICD Diagnosis Codes** are considered medically necessary when submitted with the CPT code above if **medical necessity criteria** are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip

Description

Isolated limb perfusion (ILP) is a method of drug delivery that is designed to deliver high local doses of chemotherapy while avoiding systemic toxicity. It has been investigated primarily as a treatment of malignant melanoma arising in the extremities. ILP involves the following steps: 1) mobilization and placement of venotomy and arteriotomy catheters into the major blood vessels (axillary, brachial, iliac, or popliteal artery, and vein) proximal to the tumor; 2) isolation of the limb via a tourniquet; and 3) perfusion of a chemotherapeutic drug via an extracorporeal circulation system into the affected extremity. Perfusion lasts for approximately 60 minutes. Melphalan is the drug typically used, but more recently melphalan has been combined with tumor necrosis factor (TNF) and/or interferon gamma. ILP as a treatment of melanoma has been investigated in two general settings—either as adjuvant treatment after all clinical disease has been surgically resected or as therapeutic treatment for patients with surgically unresectable disease.

ILP has also been performed in conjunction with mild hyperthermia based on the theoretical rationale that heat may potentiate the tumor-killing effect of melphalan. Hyperthermia is performed by warming the perfusate and by wrapping the treated extremity in a warming blanket. Target tissue temperature is typically 39 to 40 degrees Celsius.

In isolated limb infusion (ILI), catheters are inserted percutaneously into the axial artery and vein of the affected limb and a pneumatic tourniquet is inflated proximally. Cytotoxic agents are then infused through the arterial catheter and circulated with a syringe for 15 to 20 minutes after which the limb is flushed with a liter of Hartman's solution. Progressive hypoxia occurs, but normothermia is maintained. This procedure differs from ILP primarily by avoiding the use of an extracorporeal circulation system.

Summary

Due to the small numbers, inability to blind to treatment assignment, and potentially the lack of good comparators, there may never be a randomized control trial of either ILI or ILP. Large ILP case series have consistently reported impressive complete response rates compared to systemic chemotherapy and there is no alternative therapy that would provide a meaningful comparison.

Except for use of ILI in treatment of local recurrence of nonresectable melanoma, ILI in the treatment of melanoma is considered investigational due to lack of sufficient data concerning outcomes.

Policy History

Date	Action
3/2020	Policy updated with literature review through March 1, 2020, no references added. Policy statements unchanged.
1/2018	Clarified coding information.
11/2015	Clarified coding information.
10/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
3/2014	Coding information clarified.

11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
8/2010	Annual policy review. Changes to policy statements
9/2009	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
3/2009	Annual policy review. No changes to policy statements.
10/2008	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
9/2007	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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